

Serial No. 10/714,767

Dkt.: P0011092US

Filing Date: November 17, 2003

Title: IMPLANTABLE HEART VALVE PROSTHETIC DEVICES HAVING INTRINSICALLY CONDUCTIVE POLYMERS

REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested.

Claims 1 and 20 are amended, claims 45-56 are added, claims 7-19, 21, 23-25 and 27-43 are cancelled, and claims 4, and 44 are withdrawn from consideration. The pending claims are claims 1-6, 20, 22, 26 and 44-56.

The specification is amended to clarify the state of the art at the time the invention was made. Support for the amendments to claims 1 and 20 is found in the specification, for example, at page 7, lines 3-7. New claims 45-56 are supported by the specification in particular claims 8-19. No new matter has been added by way of this amendment.

It is respectfully submitted that upon allowance of generic claims 1 and/or 20, Applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. M.P.E.P. § 809.02. Therefore, the Examiner is respectfully requested to reconsider the withdrawal of claims 4 and 44, and consider allowance of dependent claims 45-56.

Support for the amendment "is free of a metallic filler or coating" is found in the applicants' specification at page 7, lines 3-6, where the "intrinsically conductive polymers" are defined as "polymers that are conductive *without requiring non-polymeric conductive fillers or coatings, such as metallic filler or coatings.*"

The state of the art, at the time the instant invention was made, was that the metallic filling or coating on the Ogle *et al.* device was undesirable because the metal caused, among other things, chronic inflammation leading to detachment of the tissue adjacent to the device. Thus, prosthetic devices (*e.g.*, Silzone valves from St. Jude Medical) having the metal filling or coating were not biocompatible. The evidence available indicated that the metal in the Silzone devices caused detachment of the device from the adjacent tissue. (See *e.g.*, Tozzi *et al.*, European Journal of Cardio-thoracic Surgery 19 (2001) 729-731 and Bodnar, The Journal of Heart Valve Disease 2000; 9:170-173.) Thus, the specification (citation above) along with the disclosures in the cited articles would lead a person skilled in the art to conclude that metallic fillers and coatings of Ogle *et al.* on prosthetic devices are undesirable. Therefore, the amendments reciting

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that the intrinsically conductive polymer is free of a metallic filler or coating is supported by the specification as filed. No new subject matter is added.

EXAMINER INTERVIEW

Applicants thank Examiner Stewart for his courtesy during the interviews with Applicants' attorney William F. Prout, on April 14, 2009 and April 23, 2009. The proposed amendment of claims 1 and 20 to replace the claim language "does not require" by "is free of" was discussed. The Examiner agreed with the new limitations and that the new limitations are not new subject matter. In addition the examiner requested that the specific language be added to the specification at page 7, because, the specification clearly discloses that the intrinsically conductive polymer can be free of, or not have a metallic filler or coating and that the limitations will overcome the applied prior art.

The above account is believed to be a complete and accurate summary of the telephonic interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in his next communication so that Applicants can amend or supplement the interview summary.

THE 35 US C. § 102(b) REJECTION

The Examiner rejected claims 1, 2, 5, 6, 20, 22 and 26 under 35 U.S.C. § 102(b) as being anticipated by Ogle *et al.* (U.S. Patent No. 6,190,407). This rejection is respectfully traversed.

As amended, the claims are directed to an implantable heart valve sewing prosthesis comprising a ring shaped body having a blood contacting external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square, wherein the intrinsically conductive polymer is free of a metallic filler or coating; and to an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body comprising a blood contacting external surface comprising an intrinsically conductive polymer, wherein the

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intrinsically conductive polymer does not require a metallic filler or coating. The standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its elements. Hybritech Inc. v. Monoclonal-Antibodies., 231 USPQ2d 90 (Fed. Cir. 1986); In re Dillon, 16 USPQ2d 1987 (Fed. Cir. 1990). Furthermore, there must be no difference between the claimed invention and the disclosure, as viewed by a person of ordinary skill in the art. Scripps Clinic & Res. Found. v. Genenetech, Inc., 18 USPQ2d 101 (Fed. Cir. 1991).

Independent claims 1 and 20 are amended to recite that the intrinsically conductive polymer is free of a metallic filler or coating. The cited document, U.S. patent no. 6,190,407 B1 (Ogle *et al.*), discloses a medical article having an tissue-contacting surface coated, at least in part, with an antimicrobial metal in order to reduce the "very serious and even life threatening" risk of infection following implantation, such as prosthetic valve endocarditis (PVE) (see, *e.g.*, abstract; column 1, lines 33-34; column 2, line 40 – column 4, line 7; and column 4, lines 29 – column 5, line 5). The Ogle *et al.* disclosure requires a metallic coating or filler. Thus, the claimed invention without a metallic filler or coating is not anticipated by Ogle *et al.*

THE 35 US C. § 103(a) REJECTION

The Examiner rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Ogle *et al.* in view of Carpentier *et al.* (U.S. Patent No. 4,055,861). In particular, the Examiner asserts it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical articles of Ogle *et al.* with the semiannular ring of Carpentier *et al.* This rejection is respectfully traversed.

Carpentier *et al.* do not remedy the deficiencies of Ogle *et al.* Carpentier *et al.* disclose a support for a natural human heart valve that consists of an annular or part annular semi-rigid frame, which frame can be covered by a textile sheath (abstract). Carpentier *et al.* disclose that the device can be made of polyesters such as poly(ethylene terephthalate) or poly (glycol terephthalate), polyamides such as nylon 6-6, nylon 11 or nylon 12, polyolefins, polypropylene, fluorinated polymers such as polytetrafluoro-

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ethylene, or polyvinyl chloride (column 3, lines 39-45). Carpentier *et al.* further disclose that the textile sheath can be (i) produced from a woven fabric, *e.g.*, a napped fabric or a cut velour; (ii) a knitted or braided sleeve; or (iii) made of a non-woven fabric (column 3, lines 15-18). However, there is nothing in Carpentier *et al.* that teaches or suggests an implantable heart valve sewing prosthesis comprising a ring shaped body having an external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square, wherein the intrinsically conductive polymer is free of a metallic filler or coating; or an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body comprising an intrinsically conductive polymer, wherein the intrinsically conductive polymer is free of a metallic filler or coating. Therefore, the pending claims are not obvious in view of Carpentier *et al.*

It is respectfully submitted that *prima facie* obviousness has not been established. As discussed above, neither Ogle *et al.* nor Carpentier *et al.*, either alone or in combination, disclose or suggest Applicants' claimed invention. Therefore, one of ordinary skill in the art would not be motivated to combine the teachings of the cited art so as to arrive at the presently claimed invention. Hence, the claims of the present invention are distinct from the cited art. Withdrawal of the 35 U.S.C. § 103(a) rejection of the claims is therefore proper and respectfully requested.

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Applicants' respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612-455-2564) to facilitate prosecution of this application.

Respectfully submitted on behalf of
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